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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/686,797 | 10/16/2003 | Joel E. Bernstein | 41957-102740 | 7930 |

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| EXAMINER | |
|---|---|
| AZPURU, CARLOS A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/686,797 | BERNSTEIN, JOEL E. | |
| | Examiner | Art Unit | |
| | Carlos A. Azpuru | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 2-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of the response filed 03/02/06.

The following rejection is maintained in this action:

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al.

Bernstein et al disclose a method of treating painful disorders comprising administration of civamide in a vehicle appropriate for the skin or mucosal membranes, including nasal mucosa. In particular, the reference teaches that 0.001 – 1.0% civamide is delivered (see column 2, lines 1-49). The composition itself is administered over a period of two to four weeks before administration is discontinued. The treatment of neuropathies and arthritis are disclosed at col. 3, lines 5-11. Therefore, applicant administers the same bioactive (civamide), in the same vehicles, for the same art recognized purpose, and for the same duration of time. The "long-lasting effect" or duration of pain relief is an inherent property of applicant's use of the same treatment protocol disclosed by Bernstein et al.

Applicant further argues that the reference does not teach an administration step which is resumed for a relatively short period of time after a relatively long period where treatment has stopped. Applicant is essentially claiming an interval treatment regimen over that of the standard one taught by Bernstein et al. However, Bernstein et al is clear in its teaching of the use of civamide in the art recognized treatment of the same condition. Those of ordinary skill would have found it well within their ability to modify the claimed treatment regimen in any number of ways including the interval type regimen set out in the instant claims. The result of that treatment does not appear to be different in any quantifiable manner from that of Bernstein in that the same result is achieved. Therefore, barring the submission of a comparative showing which shows unusual and/or unexpected results from changing the treatment timing of this art recognized method of treatment, it is deemed that the instant method of treatment would have been obvious given the disclosure of Bernstein et al.

***Response to Arguments***

Applicant's arguments filed 03/02/2006 have been fully considered but they are not persuasive.

Applicant argues that hindsight was used in setting out the rejection of the claims under 35 USC 103(a) over Bernstein et al and quotes the statement used in that

rejection stating that it would be obvious to modify the treatment regimen in any number of ways including interval modification. However, it was also pointed out in the action that the reference teaches the use of the same compound, for the treatment of the same medical conditions, using the same vehicles, and for the same amount of time. It is not outside the skill of the ordinary practitioner to modify the administration of a known bioactive which is art recognized to treat certain specific medical conditions within a specified time frame by any number of ways. This modification is within the ordinary skill of the ordinary medical practitioner and does not require undue experimentation. Optimization of results by modification of treatment parameters is well recognized in the medical field. As such, the request for a showing of unexpected results is not unreasonable. Applicant is claiming that the use of this interval treatment is different form what is already standard in the art. Barring a showing of unexpected and/or unusual results, there is no basis for stating that the currently claimed treatment method is not obvious over what is taught by Bernstein et al. The rejection is therefore maintained.

## *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carlos A. Azpuru
Primary Examiner
Art Unit 1615